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PCT

Attorney Docket No.: P-7938-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): JAMES, William et al. Examiner: Not Yet Known  
Serial No.: 10/534,259 Group Art Unit: Not Yet Known  
Filed: May 10, 2005  
Title: LIGANDS

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO-1449:

1. ☒ listing documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents and/or United States patent application publications are not included in this information disclosure statement; and/or
2. ☐ listing documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Serial No. \_\_\_\_\_, filed \_\_\_\_\_ which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
3. ☐ listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement;
4. ☐ listing other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a counterpart foreign application, a copy of which is included with this information disclosure statement.

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SERIAL NO.: AppNo\$  
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The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

I) ☐ Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits of the subject Application or a request for continued examination thereof, whichever event occurs last pursuant to of 37 C.F.R §1.97 (b); or

II) ☒ After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;

1. ☐ the undersigned hereby states that each item of information listed on the Form PTO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in §1.56(c) more than three (3) months prior to the filing of this information disclosure statement; or

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2. ☐ the undersigned hereby authorizes the Patent Office to charge the fee in the amount of \$180.00 under 37 C.F.R. §1.17 (p) to Deposit Account 50-3355.

III) ☒ After the period in (I) and (II) but before the payment of the issue fee and,

1. The undersigned hereby states:

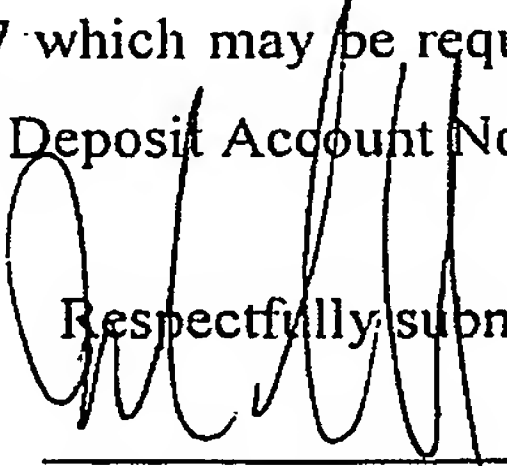
a) ☒ that each item of information cited on the form PTO-1449 was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement; or

b) ☐ that no items of information contained in Form PTO-1449 was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and

2. ☒ The undersigned hereby authorizes the Patent Office to charge the Petition fee in the Amount of \$180.00 under 37 C.F.R. §1.17 (p) to Deposit Account 50-3355.

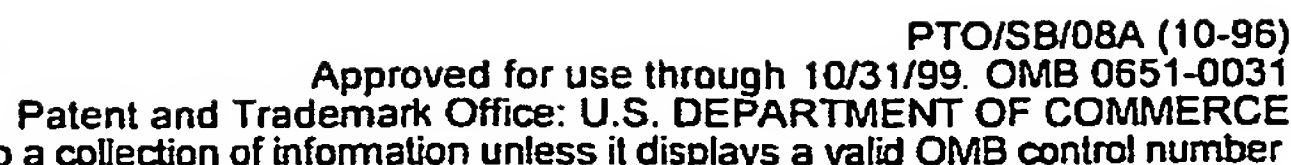

**Except** for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-3355.

Respectfully submitted,

  
Mark S. Cohen  
Attorney/Agent for Applicant(s)  
Registration No. 42,425

Dated: November 20, 2005

**Pearl Cohen Zedek Latzer, LLP**  
10 Rockefeller Plaza, Suite 1001  
New York, New York 10020  
Tel: (212) 632-3480  
Fax: (212) 632-3489



# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**Complete if Known**

<b>Application Number</b>	<b>10/534,259</b>
<b>Filing Date</b>	<b>May 10, 2005</b>
<b>First Named Inventor</b>	<b>JAMES, William</b>
<b>Group Art Unit</b>	<b>Not Yet Known</b>
<b>Examiner Name</b>	<b>Not Yet Known</b>
<b>Attorney Docket Number</b>	<b>P-7938-US</b>

Sheet	1	of	6
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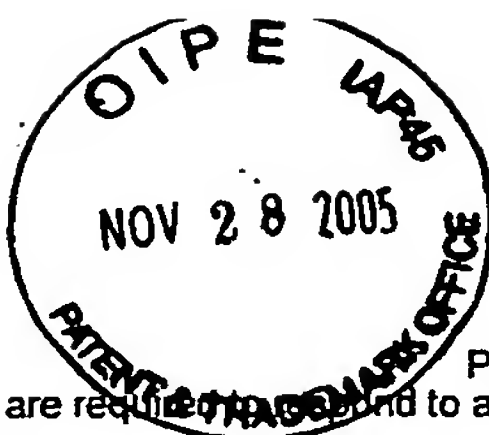
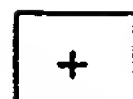
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U S Patent Documents <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST 16 if possible <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	D	<b>Arendrup, Maiken, et al</b> (1992) "Antilogous HIV -1 Neutralizing Antibodies: Emergence of Neutralization – Resistant Escape Virus and Subsequent Development of Escape Virus Neutralization Antibodies (Journal of Acquired Immune Deficiency Syndromes", Vol. 5 No. 3, 1992)	<input type="checkbox"/>
	E	<b>Barre-Sinoussi, F., et al</b> (1983) "Isolation of a T-Lymph tropic Retrovirus from a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS)", (Science, New Series, Vol. 220, No. 4599, May 20, 1983, 868-871)	<input type="checkbox"/>
	F	<b>Berger, E.A., et al</b> (1998) Nature, Vol 391, Page 240	<input type="checkbox"/>
	G	<b>Bewley, C. A., et al</b> (2002) " Design of a Novel Peptide Inhibitor of HIV Fusion That Disrupts the Internal Trimeric Coiled-coil of gp41" ( The Journal of Biological Chemistry) Vol. 277 No. 14238-14245. 25)	<input type="checkbox"/>
	H	<b>Buchacher, A., et al</b> (1994) " Generation of Human Monoclonal Antibodies of HIV-1 Proteins; Electro fusion and Epstein-Barr Virus Transformation of Peripheral Blood Lymphocyte Immortalization", (Aids Research and Human Retroviruses Vol. 10 359-69)	<input type="checkbox"/>
	I	<b>Burton, D.R., et al</b> (1991) " A Large Array of monoclonal antibodies to type 1 human Immunodeficiency Virus from Combinatorial Libraries of asymptomatic Seropositive Individuals" (Proc Natl Acad Science U S A 88, 10134-7)	<input type="checkbox"/>
	J	<b>Chan, D. C., et al</b> (1998) "Evidence That a Prominent Cavity in the Coiled-coil of HIV type 1 gp41 is an Attractive Drug Target" (Proc Nat'l Acad Science U S A 95, 15613-7)	<input type="checkbox"/>
	K	<b>Chavda, S.C., et al</b> (1994) " Molecular Determinants of the V3 Hoop of Human Immunodeficiency Virus Type 1 glycoprotein gp120 responsible for Controlling Cell Tropism" (Journal of General Virology 75 (Pt 11), 3249-53)	<input type="checkbox"/>
	L	<b>Chesebro, B., et al</b> ( 1991) "Identification of Human Immunodeficiency Virus Envelope Gene Sequences Influencing Viral Entry into CD4-Positive HeLa Cells, and Macrophages" (Journal of General Virology 65, 5782-9)	<input type="checkbox"/>
	M	<b>Ferrer, M., et al</b> (1999) " Selection of gp41 – Mediated HIV -1 Cell Entry Inhibitors From Biased Combinatorial libraries of Non – Natural Binding Elements" ( Nat Struc Biol 6, 953-60)	<input type="checkbox"/>
	N	<b>Finzi, D., et al</b> (1999) "Latent Infection of CD4 T Cells Provides a Mechanism for Liflong Persistence of HIV-1 Even in Patients Effective Combination Therapy" (Nat Med 5, 512-7)	<input type="checkbox"/>

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				Group Art Unit	Not Yet Known
(use as many sheets as necessary)				Examiner Name	Not Yet Known
Sheet	3	of	6	Attorney Docket Number	P-7938-US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	O	Gartner, S., et al (1986) "Virus Isolation From and Identification of HTLV V-III/LAV – Producing Cells in Brain Tissue From a Patient With AIDS" (J Exp Med 167, 1428-41)	
	P	Gendelman, H. E., et al (1989) " The Macrophage in the Persistence and Pathogenesis of HIV Infection" (Aids 3,475-95)	<input type="checkbox"/>
	Q	Gendelman, H. E., et al (1988) " Efficient Isolation and Propagation of Human Immunodeficiency Virus of Recombinant Colony- Stimulating Factor 1-Treated Monocytes " (J Exp Med 167, 1428-21)	<input type="checkbox"/>
	R	Gershoni, J.m., et al ( 1993) "HIV Binding to Its Receptor Creates Specific Epitopes for the CD4/gp120 complex" ( Faseb J 7, 1185-7)	<input type="checkbox"/>
	S	Karlsson, R., et al ( 1991) "Kinetic Analysis of Monoclonal antibody-antigen Interactions With A New Biosensor Based Analytical System" ( J Immunol Methods 145, 229-40)	<input type="checkbox"/>
	T	Kilby, J. M., et al (1998) Potent Suppression of HIV 1 Replication in Humans in T-20, A Peptide Inhibitor of gp41 –Mediated Virus Entry" (Nat Med 4, 1302-7)	<input type="checkbox"/>
	U	Kowalski, M., et al (1987) " Functional Regions of the Envelope Glycoprotein of Human Immunodeficiency Virus Type 1" (Science 237, 1351-5 30)	<input type="checkbox"/>
	V	Kraus, E., et al (1998) "Cutting Edge: Novel RNA Ligands Able to Bind CD4 Antigen and Inhibit CD4 T Lymphocyte Function" (J Immunol 160, 5209-12)	<input type="checkbox"/>
	W	Kwong P. D., et al (1998) "Structure of an HIV gp 120 Envelope Glycoprotein In Complex With the CD4 Receptor and Neutralizing Human Antibody" (Nature 393, 648-59 25)	<input type="checkbox"/>
	X	Kwong P. D., et al (2000) "Structure of an HIV gp 120 Envelope Glycoprotein In Complex With the CD4 Receptor and Neutralizing Human Antibody" (Structure Fold Des 8, 1329-39)	<input type="checkbox"/>
	Y	Lin C. L., et al (2000) "Macrophage Tropic HIV Induces an Exploits Dendritic Cell Chemotaxis" (J Exp Med 197, 587-94)	<input type="checkbox"/>

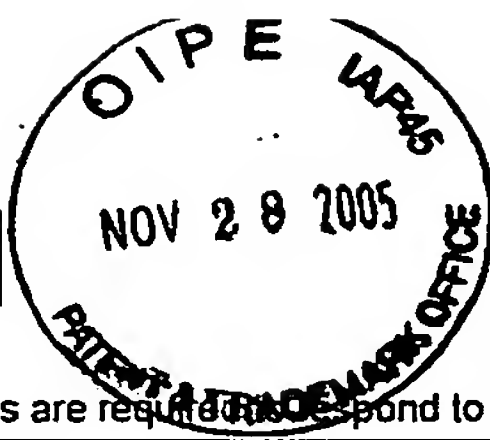
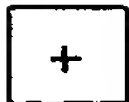
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	Z	McKeating, J.A., et al (1989) "Characterazation of HIV 1 Neutralization Escape Mutants" (Aids 3, 777-84)	<input type="checkbox"/>
	AA	Michael, N. L., et al (1999) "HIV-1 Entry Inhibitors: Evading the Issue" (Nat Med 5, 740-2)	<input type="checkbox"/>
	BB	Mondor, I., et al (1988) "Interactions among HIV gp120, CD4, and CXCR4: Dependence on CD4 Expression Level, gp120 Viral Origin, Conservation of the gp120 COOH and NH2 Termini and V1/V2 and V3 Loops, and Sensitivity of Neutralizing Antibodies" (Virology 248, 394,-405)	<input type="checkbox"/>
	CC	Moore, J. P., et al (1990) "Characterization of Recombinant gp120 and gp160 from HIV-1: Binding to Monoclonal Antibodies and Soluble CD4" ( Aids 4, 307-15)	<input type="checkbox"/>
	DD	Moore, J. P., et al (1990) "HIV-1 Naturalization: The Consequences of Viral Adaption to Growth on Transformed T Cells" (Aids 9, S117-36)	<input type="checkbox"/>
	EE	Mosier, D., et al (1994) "Macrophage-tropic HIV: Critical for AIDS Pathogenesis?" (Immunol Today 15, 332-9	<input type="checkbox"/>
	FF	Pagratis, N. C., et al (1997) "Potent 2', and 2-Fluore-2-Deoxyribonucleotide RNA Inhibitors of Keratinocyte Growth Factor" (Nat Biotechnol 15, 68-73)	<input type="checkbox"/>
	GG	Pilgrim N.C., et al (1997) "Neutralizing Antibody Responses To Human Immunodeficiency Virus Type 1 in Primary Infection and Long Term – Non progressive Infection" (Nat Biotechnol 15, 68-73)	<input type="checkbox"/>
	HH	Ping, L. H., et al (1999) "Characterization of V3 Sequence Heterogeneity In Subtype C Human Immunodeficiency Virus Type 1 Isolates from Malawi: Under representation of X4 Variants " (Nat Biotechnol 15, 68-73)	<input type="checkbox"/>
	II	Piot, P., et al (2001) "The Global Impact of HIV/AIDS" (Nature 410, 968-73	<input type="checkbox"/>
	JJ	Prince, A. M., et al (1991) "Prevention of HIV Infection by Passive Immunization With HIV Immunoglobulin" (Aids Res Hum Retroviruses 7, 971-3)	<input type="checkbox"/>

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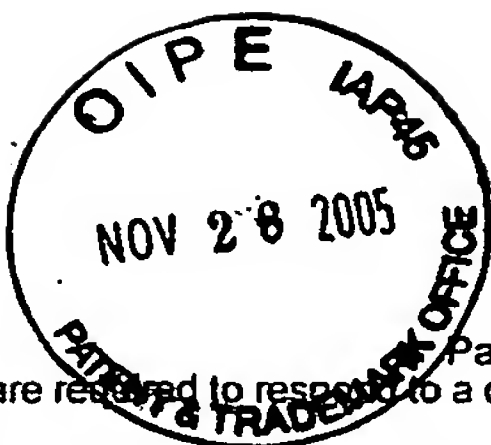
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	KK	Rizzuto C. D., et al (1998) "A Conserved HIV gp 120 Glycoprotein Structure Involved in Chemokine Receptor Binding" (Science 280, 1949-53)	<input type="checkbox"/>
	LL	Sullivan, N., et al (1998) "CD4-Induced Conformational Changes in the Human Immunodeficiency Virus Type 1 gp120 Glycoprotein: Consequences for Virus Entry and Neutralization" (J Virol 72, 4694-703)	<input type="checkbox"/>
	MM	Sayer, N., et al (2002) Biochem Biophys Res Comm in press	<input type="checkbox"/>
	NN	Tahiri-Alaoui, A., et al (2002) "High Affinity Nucleic Acid Aptamers for Streptavidin Incorporated into Bi Specific Capture Ligands" (Nucleic Acids Research 30, 1-9 35)	<input type="checkbox"/>
	OO	Thali, M., et al (1993) "Characterization of Conserved Human Immunodeficiency Virus type 1 gp120 Neutralization Epitopes Exposed upon gp120-CD4 binding" (J Virol 67, 3978-88)	<input type="checkbox"/>
	PP	Trkola, A., et al (2002) "HIV-1 Escape From a Small Molecule, CCR5-Specific Entry Inhibitor Does Not Involve CXCR4 Use" (Proc Natl Acad Sci U S A 99, 395-400)	<input type="checkbox"/>
	QQ	Wyatt, R., et al (1995) "Involvement of the V1/V2 Variable Loop Structure In The Exposure of Human Immunodeficiency Virus Type 1 gp120 Epitopes Induced by Receptor Binding" (J Virol 69, 5723-33)	<input type="checkbox"/>
	RR	Zollner, B., et al (2001) "Primary Genotypic Resistance of HIV-1 to the Fusion Inhibitor T-20 in Long-term Infected Patients" (Aids 15, 935-6)	<input type="checkbox"/>
	SS	Zwick, M.B., et al (2001) "Neutralization Synergy of Human Immunodeficiency Virus Type 1 Primary Isolates by Cocktails of Broadly Neutralizing Antibodies" (J Virol 75, 12198-208)	<input type="checkbox"/>
	TT	Kilby, J. M., et al (1998) "Potent Suppression of HIV-1 Replication in Humans by T 20 a Peptide Inhibitor of gp41 mediated Virus Entry" (Nat Med 4, 132-7)	<input type="checkbox"/>
	UU	Coilin, M., Herbein, G., Montaner, L. & Gordon, S. (1993) "PCR ananlysis of HIV1 infection of macrophages:virus entry is CD4-dependent" Res Virol 144, 20 13-9.	<input type="checkbox"/>

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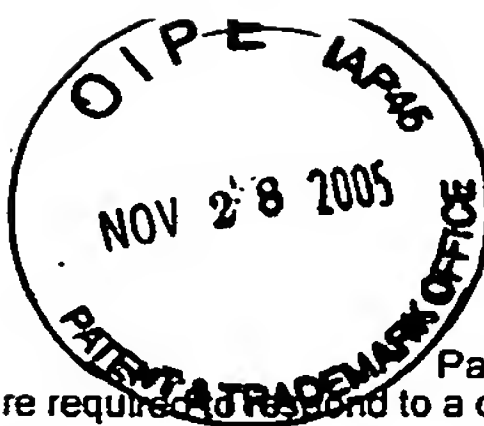
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	VV	<b>Fitzwater, T. &amp; Polisky, B.</b> (1996) "A Selex Primer" Methods Enzpol 267, 275-301.	<input type="checkbox"/>
	ww	<b>Collin, M., Illei, P., James, W. &amp; Gordon, S.</b> (1994)"Definition of the range and distribution of human immunodeficiency virus macrophage tropism using PCR-based infectivity measurements" J Gen Virol 75, 1597-1603.	<input type="checkbox"/>
	XX	<b>Borrow, P., Lewicki, H., Wei, X., Horwitz, M. S., Pfeffer, N., Meyers, H., Nelson, J. A., Gairin, J. E., Hahn, B. H., Oldstone, M. B. &amp; Shaw, O. M.</b> (1997) Nat Med 3,205-11.	<input type="checkbox"/>
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Examiner Signature		Date Considered	
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\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609 Draw line through citation if not in conformance and not considered Include copy of this form with next communication to applicant

<sup>1</sup> Unique citation designation number <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached

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